

Appl. No.: 10/018,731
Group Art Unit: 1711
Applicants' Response to Paper No. 12

REMARKS

Claims 23-38 are currently pending in the present application.

In Paper No. 12, the Examiner rejects claim 23 under 35 U.S.C. §102(b), as being clearly anticipated by U.S. Pat. No. 5,116,747 of Moo-Young, *et al.* (hereinafter referred to as "Moo-Young"). Specifically, the Examiner contends that Moo-Young discloses the immobilization of biologically active material in capsules prepared from a water-soluble polymer and chitosan acetate. The Examiner further contends that Moo-Young discloses the final capsules as having a diameter of from about 500 to about 3,000 microns. On these bases, the Examiner argues that the claimed invention is anticipated.

Applicants respectfully traverse the Examiner's rejection, along with the contentions and arguments set forth in support thereof, for the following reasons.

To begin with, in order for a rejection under 35 U.S.C. §102 to be proper, each and every element of the claimed invention must be taught, either expressly or inherently, in a single prior art reference. (*See, e.g.*, M.P.E.P. §2131). Applicants submit that Moo-Young fails to teach each and every element of the claimed invention.

Applicants' claimed invention is directed to microcapsules having a mean diameter of from about 0.1 to about 5 mm, a membrane and a matrix containing at least one active principle wherein the microcapsule is the product of the process comprising the steps of (a) forming a an aqueous matrix by heating an aqueous solution comprised of a gel former, a chitosan and active principle; (b) forming a dispersed matrix by adding the aqueous matrix in an oil phase; (c) contacting the dispersed matrix with an aqueous solution of an anionic polymer selected from the group consisting of a salt of alginic acid and an anionic chitosan derivative.

Moo-Young is directed to the immobilization of biological cells and biologically active materials. According to Moo-Young, immobilization allows the biologically active materials to be used in bioreactors. (*See*, Moo-Young, col. 1, lines 40-45). Immobilization involves the formation of "a solid immobilizing medium". (*See, id.* at lines 58-61). Moo-Young discloses a variety of methods for "immobilizing" the biological cells, including a method referred to as "encapsulation." Moo-Young discloses that in the encapsulation embodiment of

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the disclosed invention, "the cells are encapsulated within an outer semi-permeable membrane." (See, Moo-Young, col. 2, lines 18-20). Moo-Young appears to disclose the production of coated cells, not microcapsules containing a matrix of an active principle, chitosan and a gel former.

Moo-Young discloses the suspension of cells in an aqueous solution of a polyanionic polymer, such as sodium alginate. (See, *id.* at lines 32-35). This suspension is then contacted with chitosan to form a membrane around the cells.

In contrast, Applicants' claimed invention is directed to a microcapsule having a matrix which comprises an active principle, chitosan and a gel former. This matrix is then contacted with an aqueous solution of an anionic polymer to form a membrane. Accordingly, in the present invention, the "encapsulated" matter is a combination of an active principle, chitosan and a gel-former. Moo-Young, on the other hand, discloses the encapsulation of biological cells with a membrane. There is no teaching in Moo-Young of an encapsulated matrix comprising an active principle, chitosan and a gel former.

Applicants respectfully submit that Moo-Young fails to teach each and every element of the claimed invention. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b), based upon Moo-Young are respectfully requested.

In Paper No. 12, the Examiner provisionally rejects claim 23 under 35 U.S.C. §101, as claiming the same invention as that of claim 1 of copending U.S. Pat. Application Nos. 10/018,866; 10/220,718; and 10/018,922 (hereinafter referred to as "the '866 application", "the '718 application" and "the '922 application", respectively).

Applicants would like to inform the Examiner that claims 1-10, 1-19 and 1-22 in the copending applications had been canceled and replaced with new claims via preliminary amendments. If the Examiner requires copies of the currently pending claims, Applicants request that the Examiner contact Applicants' undersigned representative.

In any event, in the '718 application, claim 11 is now pending and is directed to a microcapsule comprising an o/w emulsion encapsulated in a matrix of an anionic polymer contacted with chitosan. The matrix comprising the o/w emulsion and the anionic polymer is different than the instantly claimed matrix comprising an active principle, chitosan and a gel

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former. In the '866 application and the '922 applications, the currently pending microcapsule claims, claims 20 and 23 respectively, are directed to microcapsules wherein the encapsulated matrix comprises a gel former, an anionic polymer, an anionic chitosan derivative and an active principle. In contrast, the present claims are directed to the encapsulation of a matrix comprising a gel former, chitosan and an active principle, by contacting the matrix with an anionic polymer. Accordingly, the copending applications are different in that the anionic polymer is part of the matrix therein, whereas in the present invention the anionic polymer forms the membrane.

Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §101, based upon the copending applications.

In Paper No. 12, the Examiner provisionally rejects claims 24-38 under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 2-10 and 2-22 of the '866 application, the '718 application and the '922 application. Specifically, the Examiner acknowledges that the "conflicting claims" are not identical, but argues that they are not patentably distinct because,

"the minor differences in the recitations of the claims are not patentably distinct over each other. In essence, the claims are obviously the same and do not distinguish over each other."
(See, Paper No. 7, pp. 2-3).

On this basis the Examiner contends that the instant claims are not patentably distinct over the claims of the '866 application, the '718 application and the '922 application. Applicants respectfully traverse the Examiner's rejection, along with the contentions and arguments in support thereof for the following reasons.

As mentioned above, claims 1-10, 1-19 and 1-22 in the copending applications have been canceled and replaced with new claims via preliminary amendments. However, the newly presented process claims in the copending applications are in fact different from the present claims. Contrary to the Examiner's assertions, the present claims are not obvious in view of the pending process claims in the copending applications.

The process embodiments of Applicants' claimed invention are directed to processes comprising the steps of (a) forming a an aqueous matrix by heating an aqueous

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solution comprised of a gel former, a chitosan and active principle; (b) forming a dispersed matrix by adding the aqueous matrix in an oil phase; (c) contacting the dispersed matrix with an aqueous solution of an anionic polymer selected from the group consisting of a salt of alginic acid and an anionic chitosan derivative.

On the other hand, the process claims of the '866 application and the '922 application are directed to processes wherein an aqueous matrix is formed by heating an aqueous solution of a gel former, an anionic polymer, an anionic chitosan derivative and an active principle. This is clearly different than the instantly claimed step of forming a an aqueous matrix by heating an aqueous solution comprised of a gel former, a chitosan and active principle. The process claims of the '718 application are directed to the initial formation of an o/w emulsion which is then combined with an aqueous solution of an anionic polymer to form a matrix for encapsulation. Again, this is clearly different than the presently claimed matrix forming step.

Applicants respectfully submit that the present claims are not obvious in view of the copending applications' claims. Accordingly, the present claims are patentably distinct from those of the copending applications. Reconsideration and withdrawal of the Examiner's rejection under the judicially-created doctrine of obviousness-type double patenting are requested.

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In view of the remarks set forth above, Applicants submit that all pending claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejections and a Notice of Allowance are respectfully requested.

Respectfully submitted,

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February 4, 2004
(Date)

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